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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/512,593	02/23/2000	John W. Eaton	5050/651	3307

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EXAMINER
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RAMIREZ, JOHN FERNANDO

ART UNIT	PAPER NUMBER
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3737

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10/28/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/512,593	<b>Applicant(s)</b> EATON ET AL.	
	<b>Examiner</b> JOHN F. RAMIREZ	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09/24/08.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) 77 and 80-88 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-19, 24-26, 55-62 and 66 is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-11, 20-23, 27-32, 35-40, 63, 64, 67, 68, 75, 76, 78 and 79 is/are rejected.
- 7) ☒ Claim(s) 6, 12-14, 33, 41-54, 65 and 69-74 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Response to Amendment*

Applicant's arguments filed ON 09/24/08 have been fully considered but they are not persuasive.

Claims 1-76 and 78-79 are rejected under 35 U.S.C. 251 for the following reasons:

(1) Declaration

The Reissue Declaration filed 2/23/2000 failed to properly identify at least one 35 U.S.C.251 error. It is not sufficient for an oath /declaration to merely state "...New claims 76-79 depend from claim 1 and add subject matter further defining the claimed invention. I believe that I claimed more or less than I had a right to claim. Accordingly, the lack of claims directed to the limitations of these new claims constitutes an error by claiming a different scope of claim coverage than I had a right to claim. The errors cited above for new claims 76-79, including claiming less than I had a right to claim, arose without any deceptive intention on my part". New claims 80-88 were not originally claimed. Independent new claim 80 corresponds to claim 1 with "a second ultrasonic transducer array disposed in the distal end region of the body" deleted; -catheter-- was added before "body having a longitudinal"; and -an absolute sensor disposed in the distal end region of the body--was added". These reasons are no longer exist today because claims 77, 80-88 have been cancelled by the examiner amendment.

Rather, the oath /declaration must specifically identify an error. Any error in the claims must be identified by reference to the specific claim(s) and the specific claim language wherein lies the error. (MPEP 1414 II. (C)). Therefore, a new reissue declaration in compliance with 37 CFR 1.63 is required to set forth the errors corrected by the examiner's amendment.

The Reissue Declaration must state (a) state that the person making the oath or declaration believes the named inventor to be the original and **first inventor** of the invention claimed as required by 37 CFR 1.63(a)(4); (b) state that the person making the oath or declaration has reviewed and understands the contents of the application, including the claims, **as amended by any amendment specifically referred to in the oath or declaration** as required by 37 CFR 1.63(b)(2); and (c) state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to **patentability** as defined in § 1.56 as required by 37 CFR 1.63(b)(3). To cure this defect, applicant may use Form PTO/SB/51 may be downloaded in USPTO Website.

(2) Supplemental Declaration

A supplemental oath/declaration under 37 CFR 1.175(b)(1) is needed to cover errors corrected by examiner amendment of 5/30/06 (add or delete limitations in claims and add or delete claims after filing the Declaration on 2/23/2000). Form paragraph 14.05.02 may be used for this matter. To cure this defect, applicant should use Form PTO/SB/51S maybe downloaded from the USPTO Website. See MPEP §1444 for handling supplemental oaths/declarations.

The reissue claims broaden the scope of the patented claims in at least one respect even though they are narrower in other respects. MPEP 1412.03(I). Therefore, the Supplemental Declaration must be signed by all inventors (not the assignee). MPEP 1414.01 (III). See also *In re Hayes*, 53 USPQ 2d 1222

***Claim Objections***

The claims need amendment with respect to the following:

(a) Amendment in examiner's amendment of 5/30/06 failed to comply with 37 CFR 1.173(c). Pursuant to 37 CFR 1.173(c), each amendment submitted must set forth the status of all patent claims and all added claims as of the date of the submission. (MPEP 1453 (II)). Amendment submitted 4/25/05 failed to include a complete listing of all of the claims with status identifier.

(b) Examiner Amendment of 5/30/06 failed to comply with 37 CFR 1.173(b)(2). All amendments in the reissue application must be made relative to (i.e., vis- à-vis) the patent specification in effect as of the date of the filing of the reissue application. The patent specification includes the claims and drawings. All amendments subsequent to the first amendment must also be made relative to the patent specification in effect as of the date of the filing of the reissue application, and **not** relative to the prior amendment (37 CFR 1.173(g)). Therefore, claims 1, 7 and 20 of the examiner's amendment filed 5/30/06 need to be underlined". Form paragraph 14.21.01 may be used for this 37 CFR 1.173(b) informality.

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1, 75-76 and 78-79 are again rejected under 35 USC103(a) as obvious based upon Bechai et al. (US 4,417,583) or linuma (US 5,450,850), in either case further in view of Seward et al (US 5,699,805 of record) and/or Eberle et al (US 5,368,037 of record).**

Bechai et al as well as linuma teach inclusion of both endfire 50 or A and sidefire 48 or B arrays at the tip of a catheter-like probe for driving selective displays. Whereas they do not respectively refer to their device as a catheter, it would have been obvious in view of Seward et al which teaches an ultrasound catheter including as plurality of

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(longitudinal) linear phased arrays at the distal end that a device such as in Bechai et al is in fact a catheter of esophageal-inserted type. In the alternative, it would have been obvious in view of Eberle et al to provide such end or side-fire arrays on an ultrasound (intravascular) catheter since these were also known to provide scan information from within vessel walls (Claims 1, 75). Seward et al makes clear in col. 6, lines 11-22 that the disclosed catheter is usable inside the blood vessel or inside a cavity such as the esophagus where upon it would have reasonably been called a transesophageal imaging catheter.

Eberle et al teaches that when arrays are adapted for an intravascular catheter the imaging catheter may be made as small as 1 mm diameter, see col. 11, lines 65-68. (Claims 76, 78-79).

**Claims 2-4, 27-29, 35-36 are again rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, or in the case of Bechai et al further in view of linuma (US5450850).** Whereas only Seward et al refer to their array as a phased (and also planar) array, it would have been obvious in view of linuma Figs. 15-16 and col. 13, lines 11-28 to provide phasing to both a longitudinal linear and a generally radial or annular array on the tip of a (catheter or catheter-like) probe since this allows resolution for an image in two geometries (claim 2).

Both Seward et al and linuma teach linear arrays oriented such that the scan azimuth is parallel to the longitudinal array axis (claim 3).

In linuma for example the reversal of the two arrays proximal to distal would be inherently obvious since the perpendicular array orientations merely provide three-dimensional information from closely adjacent positions which is achievable in either order of array, proximal to distal (claims 4, 35-36).

**Claims 5 and 30-31, 38-40 and 67 are again rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 2, 35 above, and further in view of Kitney et al (US5081993 of record)** since whereas the former are silent as to the use of an additional radial array, Kitney et al Fig. 4 vs Fig. 3 details that an additional radial array may be added to a catheter device in order that 3D scanning may be rapidly had by energizing sub-arrays in more than one plane simultaneously. (Claims 5, 30- 31, 38-40).

Kitney et al further teaches that a position sensor may be included in such a catheter tip, see col. 12, lines 31-64 (Claim 67).

**Claim 68 is again rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 67 above, and further in view of Martinelli (US4821731 ).**

Whereas Kitney et al teach a radiographic and a spark-gap position-sensing alternative, it would have been obvious in view of Martinelli et al to provide a magnetic position sensing tip in order to provide the position location called for in Kitney et al since this was a well-known sensor alternative.

**Claims 10, 32, 37 are again rejected under 35 USC 103(a) as obvious based upon the references as applied against claims 2 or 5 or 36 above, and further in View of Fujio et al (US5471988).**

Whereas the former do not discuss forward curving of the linear array around the catheter tip, it would have been obvious in view of Fujio et al Fig.55A element 347 to do so since this would provide the viewing array to forward look in linuma while allowing a blunt rounded tip penetration profile in Bechai et al.

**Claims 7 -9, 11 are again rejected under 35 U.S.C. 103(a) as being unpatentable over linuma and Seward et al.**

Both references teach use of plural arrays on the distal tip of a catheter-like device with displays for viewing the scans therefrom; in linuma a combined radial and longitudinal phased array pair is taught. Since Seward et al phased array catheters as suitable for intravascular use while linuma teaches transmit and receive beamformers 13, 23 for association with phased longitudinal and radial arrays such as Figs. 15-1, either reference may serve as a base reference modified by the other.

**Claims 20-23, 63-64 are again rejected under 35 U.S.C. 102(b) as obvious over linuma in view of Seward et al.**

Since linuma computes ejection fraction based upon imaging of cardiac structure with a conventional extra-thoracic probe 16, the tomography-based aortic area



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determinations done by the dual linear and at least partly radial arrays of probe 121 are in effect part of a cardiac structure imaging method, whereupon Seward et al. is merely relied upon to evidence that probe 121 of linuma would be designated a catheter.

### ***Allowable Subject Matter***

Claims 6, 12-14, 33-34, 41-54, 65 and 69-74 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 15-19, 24-26, 55-62 and 66 are allowed.

The offer filed on 2-23-2000 to surrender the original patent is again noted.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN F. RAMIREZ whose telephone number is (571)272-8685. The examiner can normally be reached on (Mon-Fri) 7:00 - 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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